

1614
IPW



PATENT

Attorney Docket No.: 18184-0018-01-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent Application of : Group Art Unit: Not Yet Assigned
Steven M. Leventer, *et.al.* :
Serial No: 10/578,522 : Examiner: Not Yet Assigned
Filed: May 8, 2006 :
For: TREATMENT OF INFLAMMATORY :
DISORDERS OF THE EPITHELIUM WITH LOW :
DOSE 2,3-BENZODIAZEPINES :

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, submitted herewith are copies of the references listed in the accompanying form PTO-1449, except for any U.S. patents and published U.S. patent applications which may be listed.

The Examiner is respectfully requested to review the items listed on the PTO Form 1449 and make them of record in the instant application as required by M.P.E.P. §609. It is requested that the Examiner initial the enclosed duplicate substitute Form 1449, and return one copy to the undersigned.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)	
I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
BY	<u>Jennifer K. Harra</u>
DATE:	7/21/06

This Information Disclosure Statement should not be construed as a representation that the cited references are material or prior art, or that more relevant references do not exist.

This statement is being submitted before receipt of any office action on the merits. Thus, no fee is due for the filing of this paper. However, if a fee is due, please charge deposit account 50-0573.

Respectfully submitted,

STEVEN M. LEVENTER, *et al.*

BY


DANIEL A. MONACO

Reg. No. 30,480

DRINKER BIDDLE & REATH LLP

One Logan Square

18th and Cherry Streets

Philadelphia, PA 19103-6996

Tel.: (215) 988-3312

Fax: 215) 988-2757

Attorney for the Applicants

SUBSTITUTE FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
18184-0018-01-USSERIAL NO.
10/578,522

INFORMATION DISCLOSURE STATEMENT

APPLICANT:
Steven M. Leventer, et al.FILING DATE
May 8, 2006GROUP
Not Yet Assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
AA	3,736,315	05/29/1973	Korosi et al.	260	239	
AB	Re. 30,014	05/29/1979	Kőrosi, et al.	260	239	
AC	4,322,346	03/30/1982	Kórósi, et al.	260	239	
AD	4,423,044	12/27/1983	Kórösi, et al.	424	244	
AE	4,614,740	09/30/1986	Láng, et al.	514	221	
AF	4,835,152	05/30/1989	Korösi, et al.	514	220	
AG	4,840,948	06/20/1989	Láng, et al.	514	221	
AH	5,204,343	04/20/1993	Andrási, et al.	514	221	
AI	5,288,863	02/22/1994	Somogyi, et al.	540	567	
AJ	5,459,137	10/17/1995	Andrási, et al.	514	220	
AK	5,519,019	05/21/1996	Andrási, et al.	514	220	
AL	5,521,174	05/28/1996	Andrási, et al.	514	220	
AM	5,639,751	06/17/1997	Andrási, et al.	514	220	
AN	5,891,871	04/06/1999	Xia, et al.	514	219	
AO	6,075,018	06/13/2000	Vágó, et al.	514	221	
AP	6,080,736	06/27/2000	Landry, et al.	514	221	
AQ	6,638,928	10/28/2003	Harris et al.	514	221	
AR	6,649,607	11/18/2003	Leventer, et al.	514	221	
AS	6,683,072	01/27/2004	Kucharik, et al.	514	211.13	
AT	6,864,251	03/08/2005	Kucharik, et al.	514	221	
AU	7,022,700	04/04/2006	Harris, et al.	514	221	
AV	2004/0138209	07/15/2004	Kucharik, et al.	514	221	
AW	2004/0138210	07/15/2004	Harris, et al.	514	221	
AX	2004/0152695	08/05/2004	Harris, et al.	514	221	
AY	2004/0157833	08/12/2004	Harris, et al.	514	221	
AZ	2004/0162284	08/19/2004	Harris, et al.	514	221	
BA	2004/0224943	11/11/2004	Leventer, et al.	514	221	
BB	2004/0229867	11/18/2004	Kucharik	514	221	
BC	2005/0075329	04/07/2005	Leventer, et al.	514	221	
BD	2005/0288277	12/29/2005	Kucharik, et al.	514	221	

FOREIGN PATENT DOCUMENTS

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
						YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SUBSTITUTE FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 18184-0018-01-US	SERIAL NO. 10/578,522
INFORMATION DISCLOSURE STATEMENT				APPLICANT: Steven M. Leventer, <i>et al.</i>	
				FILING DATE May 8, 2006	GROUP Not Yet Assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	BE	EP 0 492 485	12/31/91	Europe	C07D	491/04		
	BF	178516	3/31/83	Hungary	C07D	243/00	x	
	BG	178519	3/31/83	Hungary	C07D	24300	x	
	BH	WO 92/11262	7/9/92	WIPO	C07D	491/056		
	BI	WO 00/24400	5/4/00	WIPO	A61K	31/551		

OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

BJ	Y. Adachi <i>et al.</i> , "Use of tofisopam (Grandaxin®) in autonomic imbalance and irritable bowel syndrome", <i>Igaku to Yakugaku</i> , 1987, 18(5), 1591-94, Japan. (Translation provided.)
BK	T. Aoyagi <i>et al.</i> , <i>Yakuri to Chiryo</i> , "Clinical evaluation of tofisopam (grandaxin®) in various unidentified gastrointestinal complaints", 1992, 20(2), 295-305, Japan. (Translation provided.)
BL	S. Asano <i>et al.</i> , "Study of the efficacy and safety of grandaxin tablets in vague complaints associated with gastrointestinal conditions", <i>Shinyaku to Rinsho</i> , 1993, 42(12), 95-100, Japan. (Translation provided.)
BM	V.S. Chadwick, <i>et al.</i> , "Activation of the mucosal immune system in irritable bowel syndrome", <i>Gastroenterology</i> , 2002, 122(7), 1778-83.
BN	S.M. Collins, <i>et al.</i> , "The putative role of inflammation in the irritable bowel syndrome", <i>Gut</i> , 2001, 49(6), 743-45.
BO	M. Csillag <i>et al.</i> , "The treatment of climacteric syndrome with tofizopam (grandaxin)", <i>Ther Hung</i> , 1975, 23(4), 164-69.
BP	E. Fogassy, <i>et al.</i> , "Studies on the Properties and Structure of Optically Active 1-(3,4-Dimethoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-Benzodiazepine (Tofisopam). " in H.C. Van der Plas, <i>et al.</i> (Eds.) "Bio-Organic Heterocycles Synthetic, Physical Organic and Pharmacological Aspects", Elsevier, Amsterdam (1984).
BQ	F. Galdiero, <i>et al.</i> , "Effects of Benzodiazepines on Immunodeficiency and Resistance in Mice", <i>Life Sciences</i> , Vol. 57. No. 26, pp. 2413-2423, 1995
BR	F. Gatta, <i>et al.</i> , "Derivatives of 2,3-Benzodiazepine", <i>Il Farmaco, Ed. Sc.</i> 1985, 40, 942-
BS	H. Hanajima, "Effects of tofisopam (granaxin on irritable colon and cardiac neurosis", <i>Yakuri to Chiryo</i> , 1987, 15(5), 307-17, Japan. (Translation provided.)
BT	E. Horvath, <i>et al.</i> , "Anxiolytic 2,3-benzodiazepines, their specific binding to the basal ganglia", <i>Progress in Neurobiology</i> , 2000, 60, 309-42.
BU	S. Kalashnikov, <i>et al.</i> , "Immunomodulating effects of tofizopam (Grandaxin®) and diazepam <i>in vitro</i> " <i>Mediators of Inflammation</i> , 2002, 11, 53-59.
BV	A. Kato <i>et al.</i> , "Clinical report on grandaxin for various unidentified complaints", <i>Yakuri to Chiryo</i> , 1987, 15(8), 163-71, Japan. (Translation provided.)
BW	J. Kanto, <i>et al.</i> , "Tofizopam: a benzodiazepine derivative without sedative effect", <i>International Journal of Clinical Pharmacology, Therapy and Toxicology</i> , 1982, 20(7), 309-12.

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SUBSTITUTE FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 18184-0018-01-US	SERIAL NO. 10/578,522
INFORMATION DISCLOSURE STATEMENT		APPLICANT: Steven M. Leventer, <i>et al.</i>			
		FILING DATE May 8, 2006	GROUP Not Yet Assigned		

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)

FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO

OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

BX	S. Kishimoto <i>et al.</i> , "Clinical effect of grandaxin on dyspeptic patients", <i>Yakuri to Chiryo</i> , 1989, 17(5): 457-64, Japan. (Translation provided.)
BY	A. Kitano <i>et al.</i> , "Clinical effect of tofisopam (grandaxin®) on vague gastrointestinal complaints", <i>Shinyaku to Rinsho</i> , 1988, 37(9), 169-73, Japan. (Translation provided.)
BZ	M. Kojima, <i>et al.</i> , "Effects of Tofisopam on Lower Digestive Tract Dysfunction", <i>Clinical Report</i> , 1996, 30(5), 989-94. (Translation provided.)
CA	Y. Matsuo, <i>et al.</i> , "Effect of Tofisopam on Experimental Ulcers", <i>Yakuri to Chiryo</i> , 1998, 16(8), 157-64. (Translation provided.)
CB	M. Osipenko <i>et al.</i> , "Role of grandaxin in the treatment of functional diseases of the gastrointestinal tract.", <i>Terapevt. Arkhiv</i> , 2000, 10, 23-27. (Translation provided.)
CC	O. Oyesanmi, <i>et al.</i> , "Hematologic Side Effects of Psychotropics", <i>Psychosomatics</i> , 199, 40(5), 414-21.
CD	A. Pakkanen <i>et al.</i> , "Comparative Study of the Clinical Effects of Tofizopam, Nitrazepam and Placebo as Oral Premedication", <i>Br. J. Anaesth.</i> , 1980, 52, 1009-12.
CE	L. Petocz, <i>et al.</i> , "The Main Pharmacological Characteristics of Grandaxin (Tofisopam, EGYT-341)", <i>Therapia Hungarica</i> , 1975, 23(4), 134-138.
CF	L. Petócz, "A tofizopam (Grandaxin®) farmakológiai hatásai", <i>Acta Pharm. Hung.</i> 1993, 63, 79-82. (Translation provided.)
CG	J. Ristelhueber, "Utility of a new anxiolytic, tofisopam, in current gastroenterology practice", <i>Revue Francaise de Gastro-Enterologie</i> , 1977, 125, 49-52, France. (Translation provided.)
CH	M. Rizzo, "Chromatographic separation of 2,3-benzodiazepines", <i>Journal of Chromatography B</i> , 2000, 747, 203-16.
CI	J. Szegő <i>et al.</i> , "Selected passages from the clinical-pharmacological and clinical trials of grandaxin", <i>Acta Pharm. Hung.</i> , 1993, 63, 91-98, Hungary. (Translation provided.)
CJ	H. Takada <i>et al.</i> , "Clinical study of grandaxin for unidentified complaints", <i>Yakuri to Chiryo</i> , 1989, 17(3), 381-92, Japan. (Translation provided.)
CK	I. Tarnawa, <i>et al.</i> , "Structure-Activity Relationships of 2,3-Benzodiazepine Compounds With Glutamate Antagonistic Action", <i>Bioorg. & Med. Chem. Lett.</i> , 1993, 3(1), 99-104.
CL	E. Tomori, <i>et al.</i> , "Investigation of Metabolites of Tofizopam in Man and Animals", <i>Pol J. Pharmacol. Pharm.</i> , 1984, 38, 423-30.
CM	E. Tomori, <i>et al.</i> , "Investigation of the Metabolites of Tofizopam in Man and Animals by Gas-Liquid Chromatography-Mass Spectrometry", <i>Journal of Chromatography</i> , 1982, 241, 89-99.
CN	J. Visy, <i>et al.</i> , "The Role of Configuration and Conformation in the Binding of 2,3-Benzodiazepines to Human Serum Albumin", <i>Chirality</i> , 1989, 1, 271-75.
CO	K. Yamaguchi <i>et al.</i> , "Tofisopam, a new 2,3-benzodiazepine. Inhibition of changes induced by stress loading and hypothalamic stimulation", <i>Can. J. Physiol. Pharmacol.</i> , 1983, 16, 619-25.

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SUBSTITUTE FORM PTO-1449	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 18184-0018-01-US	SERIAL NO. 10/578,522
INFORMATION DISCLOSURE STATEMENT		APPLICANT: Steven M. Leventer, <i>et al.</i>	
		FILING DATE May 8, 2006	GROUP Not Yet Assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)

FOREIGN PATENT DOCUMENTS

OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

EXAMINER	DATE CONSIDERED
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	